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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,062	06/20/2001	Herbert Lapidus	364.31	1692

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FITZPATRICK CELLA HARPER & SCINTO  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

[REDACTED] EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
1617	[REDACTED]

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/884,062	LAPIDUS, HERBERT
	<b>Examiner</b>	<b>Art Unit</b>
	Gina C. Yu	1617

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 October 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3,4,7-10 and 13-30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3,4,7-10 and 13-30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Receipt is acknowledged of Amendment filed on October 26, 2002. Claim rejections under 35 U.S.C. § 112 are withdrawn in view of applicants' remarks. Claim rejections under 35 U.S.C. §§ 102 and 103 are withdrawn and new rejections are made in view of the amended and newly submitted claims. Claims 1, 3, 4, 7-10, 13-30 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 limits the scope of the claim by reciting "consisting essentially of" to indicate that no other components which materially affects the basic and novel characteristics of the claimed invention. However, claim 23 fails to further limit claim 1 since, in claim 23, lubricants, chelating agents, or medicaments which can materially affect the rheology or pharmaceutical effects of a composition are added to the invention in claim 1. Claim 23 fails to further limit claim 1, and the metes and bounds of the scope of the claim limitation "consisting essentially of" as recited in claim 1 in view of claim 23 is unclear.

### ***Claim Rejections - 35 USC § 103***

Art Unit: 1617

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 26-30 are rejected under 35 U.S.C. § 103 (a) as unpatentable over Singh et al. (US 5858371) in view of Fowler et al. (US 5635469), Pregozien (US 5141803), and Jorgensen et al. (EP 1055424 A2) ("Jorgensen").

Singh teaches a pharmaceutical composition for treating anorectal and colonic diseases such as hemorrhoid that may be formulated in the form of foams, aerosols, sprays, or medicated pads. See abstract; col. 3, lines 25 – 28; col. 4, lines 41 – 44. The reference teaches that for foam and spray formulations, one or more aqueous and nonaqueous solvents, surfactants and stabilizing agents may be added. See col. 5, lines 11-13; col. 4, lines 1 –8; see instant claim 1. The actives of instant claim and 30 are disclosed in col. 3, line 59 –col. 4, line 40.

Singh fails to teach the formulation of the foaming composition.

Fowler teaches personal cleansing foams in a manually actuated pump. Examples illustrate foaming composition comprising 35-99.65 % of water, 0.1-20 % of surfactants, and 0.1-25 % of humectants such as alkylene glycol and glycerol. See Col. 2, line 58 – col. 3, line 6; Example V. Fowler further suggests to incorporate the actives such as NSAIDS, antipruritic actives, promazine, dibucaine, etc. See col. 14, line 35 – col. 16, line 25. See instant claim 29. Fowler further teaches using sponges or washcloths to form lathers and apply to the skin. See col. 2, lines 33 – 39; see instant claims 26 and 27.

Fowler fails to teach the combination of the surfactants as recited in the instant claims.

Pregozen teaches the key ingredients that are used in personal hygiene wipe products such as baby wipes. See col. 2, lines 33-49; col. 5, lines 43-50.

Cocoamphodiacetate and polysorbate 20 are said to cleanse and soothes skin.

Disodium cocoamphodiacetate is disclosed the aqueous composition in Example 3.

See also propylene glycol and disodium EDTA dihydrate in the formulation.

Jorgensen teaches mild, aqueous foamable skin cleanser comprising triethanolamine cocoyl glutamate, glycerin, and water See Examples. Triethanolamine cocoyl glutamate is the preferred foaming agent. The invention is said to provide *ultra-mildness* to skin. See p. 2, [0001]-[0018].

It would have been also obvious to the one of ordinary skill in the art to have additionally provided, along with the foaming product, a conventional substrate to apply to the foaming product to the effected area of the body as a lather-forming device and for convenience to the users, as suggested by Fowler and Pregozen. Given the general teaching of foaming composition of the Singh invention, one having ordinary skill in the art would have been motivated to looked to the prior arts such as Pregozen and Jorgensen, for mild surfactants that are suitable for skin and mucous membrane.

While applicants assert that the references fail to specifically mention bathroom tissue, examiner takes the position that the teaching of a disposable, fibrous substrate taught in Pregozen renders the limitation of the instant claim obvious.

Art Unit: 1617

2. Claims 1, 3, 4, 7, 17-10, 13, 17-21, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinski (US 6030931).

Vinski teaches a non-aerosol foaming skin cleansing product comprising an anionic surfactant an amphoteric surfactant, water. See col. 1, line 55 – col. 4, line 7. Adding emollients such as polyols, most preferably glycerin, is also taught. See col. 4, lines 22-30. See col. 4, lines 31 – 49 for the preservatives and the amount they are used. See instant claims 17-20. The reference also suggests adding vitamins, colorants, and fragrances. See col. 4, lines 50 – 54. See instant claims 21 (d) and 23.

The recitation in the preamble, “suitable for use as a vaginal or hemorrhoidal wipe agent”, is an intended use or purposes of the product which is not given patentable weight. See MPEP § 2111.02.

While the Vinski patent does not provide the specific disclosure of the formulation comprising the amount of the components as recited in the instant claims, it must be noted that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Vinski, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. The amount of the surfactants to be used would depend upon several factors such as costs and effects.

Art Unit: 1617

3. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinski as applied to claims 1, 3, 4, 7, 17-10, 13, 17-21, and 23-25 above, and further in view of Pregozien and Jorgensen.

Vinski, discussed above, fails to teach employing the specific surfactants recited in the instant claims.

Pregozien teaches the key ingredients that are used in personal hygiene wipe products such as baby wipes. See col. 2, lines 33-49; col. 5, lines 43-50. Cocoamphodiacetate and polysorbate 20 are said to cleanse and soothes skin. Disodium cocoamphodiacetate is disclosed the aqueous composition in Example 3. See also propylene glycol and disodium EDTA dihydrate in the formulation.

Jorgensen teaches mild, aqueous foamable skin cleanser comprising triethanolamine cocoyl glutamate, glycerin, and water See Examples. Triethanolamine cocoyl glutamate is the preferred foaming agent. The invention is said to provide *ultra-mildness* to skin. See p. 2, [0001]-[0018].

Given the general teaching of foaming products for anorectal or colonic treatment in Singh, one having ordinary skill in the art would have looked to the prior arts such as Pregozien and Jorgensen for mild detergents that are suitable for the mucous membrane and skin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the foaming products in Vinski by selecting the specific detergents as motivated by Pregozien and Jorgensen because of the expectation of successfully producing a mild cleansing composition.

Examiner also views that one having ordinary skill in the art would have discovered the optimum or workable weight ranges of the components ranges by routine experimentation.

4. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinski, Progozen, and Jorgensen, as applied to claims 1, 3, 4, 7-10, 13, 17-21, and 23-25 above, and further in view of Mohseni et al. (US 5431906), Evans et al. (US 6030931) and Wenninger et al. (Int'l Cosmetic Ingredient Dictionary and Handbook, 1997) ("Wenninger")

Vinski further teaches that polyalkylene glycols can be used as a moisturizing ingredient and the amount which they may be used. See col. 4, lines 7 – 21. Using guar gum as a cationic conditioning agent is disclosed in col. 4, line 66 – col. 5, line 17. See Examples for the amount of cationic conditioning agents used. Using 0.1-10 % of foam densifying agent is also taught. See col. 4, lines 55 – 65.

Jorgensen teaches the use of thickeners in Example 3 in the amount of 1 % by weight.

Vinski, Jorgensen, and Progozen fail to teach the polyalkylene glycol and xanthan gum which are recited in the instant claims.

Mohseni teaches that high molecular weight polyethylene glycols such as Polyox WSR N-12K (PEG 23M) is used as a thickener and lubrication agent in formulating a shaving soap. See col. 3, lines 24 – 41.

Evans teaches that polyalkylene glycol such as PEG 23M enhances lather performance and spreadability in a shampoo formulation. See col. 14, lines 41 – col.

15, line 42. The reference teaches that the invention is used to cleanse and condition hair and skin. See col. 1, line 61 – col. 2, line 17. Evans further teaches that xanthan gum is a well known a suspending agent, thickener or viscosity modifier. See col. 16, line 33 – col. 17, line 52.

Wenninger teaches xanthan gum is used to thicken an aqueous phase of cosmetic product. See pp. 1693 and 1695.

Given the general teaching of Jorgensen that thickeners may be added in the foaming composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the foaming composition of the combined references by adding the polyalkylene glycol as suggested by Mohseni and Evans because of the expectation of successfully producing a foaming composition with thickening, lubricating, lathering, and conditioning effect. The skilled artisan would have been further motivated to looked to the prior art such as Wenninger to for thickening agents suitable for the aqueous composition. Selection of xanthan gum would have been obvious in view of Vinski which teaches the use of gums in the foaming composition.

Examiner also views that one having ordinary skill in the art would have discovered the optimum or workable weight ranges of the components ranges by routine experimentation.

4. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh in view of Vinski.

Singh is discussed above. Singh fails to teach the specific types or the concentration of the components of the foaming composition.

Vinski, discussed above, teaches a non-aerosol foaming composition comprising surfactants, water, and emollients such as polyols.

Given the general teaching of foaming products for anorectal or colonic treatment in Singh, one having ordinary skill in the art would have looked to the prior arts such as Vinski for formulations for a foaming composition.

***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1617

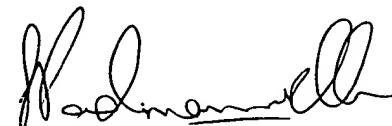
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

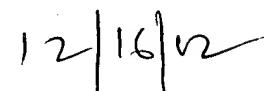
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
December 16, 2002



SREENI PADMANABHAN  
PRIMARY EXAMINER



12/16/02